



UNITED STATES PATENT AND TRADEMARK OFFICE

HL

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,938	09/29/2000	James E. McShane	FC0807Q1	1065
24265	7590	12/02/2004	EXAMINER	
SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530			SHARAREH, SHAHNAM J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. Box 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

MAILED
DEC 02 2004
GROUP 1600

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/675,938
Filing Date: September 29, 2000
Appellant(s): MCSHANE, JAMES E.

Robert J. Lipka
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on August 16, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: the rejection under 35 USC § 112, second paragraph has been withdrawn. The issue # 3 is now moot.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 32-42 do stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,122,418	Nakane et al	6-1992
5,679,324	Lisbon et al.	10-1997
5,466,470	Lajoie	11-1995

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 32-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakane US patent 5,122,418.

Nakane teaches deodorant compositions (see abstract). Nakane teaches compositions comprising micronized zinc oxide and a fragrance. The amounts of zinc oxide used in Nakane falls within the ranges of the instantly claimed compositions (col

Art Unit: 1617

10, lines 48-61, examples 24-26, 35-38). Nakane teaches the use of propellant as an aerosol deodorant spray in amounts of about 70-85% (example 31, 35, 36). Nakane's powder falls within the ranges of 1 to 100 microns wherein the zinc oxide particles have an average size of 0.01-10 microns, which is equal to 10-1000 nm. (col 5, lines 38-41; col 10, lines 19-42, col 25, lines 30-34). Thus, Nakane's particles are considered to contain micronized zinc oxide. Nakane further teaches the use of water, C₁-C₃ alcohols such as ethanol (col 10, lines 16-18; col 11, lines 42-44). Nakane does not explicitly teach the combination of zinc oxide, propellant and solvent.

It is well settled in patent law that selection of known material based on its suitability for its intended use supports a *prima facie* obviousness determination. See MPEP 2144.07. "Reading a list and select a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

Even though Nakane does not explicitly teach a combination of Zinc oxide particles, propellant with a solvent selected from group water and lower alcohols, it would have been obvious to one of ordinary skill in the art at the time of invention to employ a solvent such as water or ethanol, as suggested in Nakane, to perform their own intended use, because as reasoned in *Sinclair*, selecting such compounds to meet known requirement supports *prima facie* obviousness. Further, it would have been obvious to one of ordinary skill in the art at the time of invention to achieve the desirable concentration of each ingredient by routine experimentation.

Art Unit: 1617

3. Claims 32-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lajoie US Patent 5,466,470 in view of Lisboa et al US Patent 5,679,324.

Lajoie discloses co micronized bicarbonate salts and zinc oxide in particles sizes of 0.01 – 1.0 micron (see abstract, col 2, lines 61). Lajoie further teaches the use of zinc oxide powders in his formulations in the same amount and particles sizes as instantly claimed (see col 5, lines 1-13; col 8, lines 4-25). Lajoie also teaches the use of fragrances in his compositions (examples 3-4). Lajoie does not employ a propellant for delivery of his compositions.

Lisboa et al teaches propellant containing topical cosmetic or therapeutic compositions (see abstract). Lisboa suggests that the use of aerosol compositions gaining wide appeal among both men and women as they are easy to use (see col 1, lines 17-40). Lisboa further teaches that the use of propellants in preparing an aerosol formulation containing various cosmetically suitable ingredients is conventional. In fact, Lisboa suggests the addition of various suitable ingredients such as surfactants, thickeners, moisturizers, coolants, emollients and even sunscreen agents of choice such as zinc oxide for their known therapeutic or cosmetic use (see abstract; col 2, lines 40-67; col 3, lines 55-67; col 6, lines 14-67; col 8, lines 11-20).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add a propellant, such as those taught by Lisboa, to the compositions of Lajoie and formulate an aerosol topical delivery system of Lajoie's compositions, because one of ordinary skill in the art would have had a reasonable

Art Unit: 1617

expectation to succeed in formulating aerosolized formulations that are easy to use and are more appealing to the general consumers.

(11) Response to Argument

- A. Claims 32-42 should be rejected under 35 U.S.C. 103(a) as being unpatentable over Nakane US patent 5,122,418, because Nakane teaches all elements of the instant claims and further provide ample motivation to employ a propellant with a zinc oxide containing formulation. Appellant has not met the burden of proving nonobviousness.**

Appellant's arguments with respect to the obviousness rejection over Nakane have been fully considered but are not persuasive for the reasons set forth below.

Appellant argues that Nakane's composite powder is covered with one or more types of organic, inorganic or metallic powders (see Arguments at page 4). In response Examiner states that the instant claims employ the transitional phrase "consisting essentially of." This phrase excludes the use of active ingredients that would materially affect the basic and novel characteristics of the claimed composition. (see MPEP 2111.03). Nevertheless, for the purposes of searching and applying prior art, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. See *Id.* also *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1355, 48 USPQ2d 1351, 1355, (Fed. Cir. 1998). Here, Appellant has not provided any evidence to show otherwise. Thus, Appellant has not met the burden of proving that the zinc oxide containing compositions of Nakane are materially different from those of the instant claims.

Art Unit: 1617

Appellant further argues that Nakane's deodorant comprise of a synthetic resin powder or can contain an additional active ingredient such as a "metal oxide" or hydroxyapatite. (see *Id.*). Again, in response, Examiner states that the recited elements in Nakane's compositions are not viewed to modify the novel characteristics of what is actually claimed here. In Example 25, Nakane teaches compositions comprising zinc oxide covered with a polymer and further contains surfactants, fragrances or other conventional additives. (see col 25-26). None of such ingredients are viewed to materially change the novelty of the instantly claimed compositions. In fact, the instant claims 33-36 allows for incorporation of fragrances, thickening agents and pH modifiers into the compositions of claim 32. Appellant has not provided any evidence showing the contrary. Thus, the Appellant has not met the burden of proof.

Appellant then argues that Nakane's examples do not disclose aerosol deodorant sprays with zinc oxide. (see Arguments at page 4). In response, Examiner states that had Nakane showed such teachings, it would have been used as an anticipatory prior art. However, the instant rejection is made under the 35 USC 103 (a) obviousness analysis. Here, all elements of the claims are taught in the reference, there is ample motivation to combine the teaching of the reference, and the ordinary skill in the art would have had reasonable expectation of success in combining the teachings. Thus, Examiner has satisfied the burden of obviousness under the *Graham v. Deere* analysis.

Appellant further appears to be arguing that Nakane's compositions do not contain the specific amounts of zinc oxides instantly claimed. (see Arguments at page 4, 3rd para.). In response, Examiner states that at least example 34 of Nakane, teaches

compositions containing zinc oxide in amounts of about 25%. In fact, contrary to Appellant's statements, examples 34 and 37 clearly employ 50 g of zinc oxide in the composite powder that is used to formulate a deodorant powder. (see col 30, lines 40-60; col 31, lines 40-56). Such amounts fall within the scope of the instant claims. Appellant has not shown any evidence showing otherwise, thus, Appellant has not met the burden of proving nonobviousness.

Appellant also argues that the Examiner's reliance on the holding of *Sinclair & Carroll Co. v. Interchemical Corp*, 325 U.S. 327 (1945), have been fully considered but are not found persuasive. Appellant argues that the ruling "is a case of notorious era in the history of patent law where the Supreme Court took a very anti-patent stance." (see Arguments at page 6). In response, Examiner states that *Sinclair* has not been yet overturned and is still competent law. Accordingly, Examiner's reliance on the factual and legal analysis is reasonable.

For the reasons set forth above, the claims should stand rejected.

B. Claims 32-43 should be rejected under 35 U.S.C. 103(a) as being unpatentable over Lajoie US Patent 5,466,470 in view of Lisboa et al US Patent 5,679,324, because all the elements of the instant claims are described by the cited references and both references provide ample motivation in the art to prepare aerosolized formulations for topical delivery.

Appellant arguments have been fully considered but are not persuasive. As the initial matter, Appellant has made numerous arguments against the references individually (see Arguments at pages 6-8). One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck &*

Art Unit: 1617

Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, all the elements of the instant claims are described by the cited references. Both references provide ample motivation in the art to prepare aerosolized formulations for topical delivery. Thus, the rejection is proper.

Appellant argues that Lajoie discloses a "co-micronized" bicarbonate salt composition comprising a blend of ingredients that can include zinc oxide. (see Arguments at page 6). In response, Examiner states that the "co-micronized" particles of Lajoie are not excluded from the scope of the instant claims, because the bicarbonate salt does not materially change the novel characteristics of the instant claims.

Bicarbonate salts are viewed to fall within the scope of the instant base that neutralizes any organic or inorganic acids (see instant claim 35 and instant specification at 6, lines 25-27). Therefore, they are expected to materially maintain the novel characteristics of the instant particles. Thus, the particles of Lajoie falls within the scope of the zinc oxide particles of the instant claims.

Appellant also argues that Lisboa does not provide a general desirability of formulations containing propellant. (see Arguments at page 7). In response Examiner states that Lisboa provides that fluorocarbon propellants are well known in the art to be used in shaving creams, and other foaming products including shower, sun, foot, hand, skin and fragrance products. (see col 1, lines 14-35; col 8, line15-19). See col 1, lines 7-18 of Lisboa where it states:

Cosmetic aerosol foam compositions, particularly those used in association with shaving are well known in the art.

Therefore, relying on such conventional mode of topical delivery systems, the rejection of record concluded that converting Lajoie's formulation, the primary reference, into an aerosolized delivery system would have been an obvious modification because there is ample motivation in the art to employ such delivery system to either comply with the appeal of the customer or reduce the irritation of customer's skin. Appellant has not provided any evidence showing the contrary, thus, the rejection should stand.

Appellant also argues that nowhere in Lisboa teaches that the use of propellants in preparing aerosol formulations containing various cosmetically suitable ingredients is conventional. (see Arguments at page 7). Appellant argues that Examiner has not demonstrated where in the cited references one of ordinary skill in the art would have been "strongly motivated" to make the claimed composition. (see Arguments at page 9).

In response to appellant's argument, Examiner states that the test of obviousness does not gauge into the degree of motivation or desire of one of ordinary skill in to modify the prior art. Rather, the test evaluates some teaching, suggestion, or motivation to modify the prior art "either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, aside from the specific teachings in Lajoie and Lisboa that suggest the use of propellants for topical delivery of cosmetic agents; the knowledge generally available to one of ordinary skill in the art would have also provided ample motivation to combine the teachings of Lajoie and Lisboa to reach the instant claims. First, Lajoie

clearly states that his zinc oxide/bicarbonate particles reduces skin irritation and improves esthetics in cream, lotions, gels, ointment, toothpastes, solutions or the like. (see col 4, lines 33-37; col 7, lines 20-25). At least the "or the like" phrase suggests to one of ordinary skill in the art that alternative types of formulations may be used for delivery of zinc oxide/bicarbonate particles.

Second, Lisboa teaches that aerosolized shaving formulations are gaining wide appeal among both men and women (see col 1, lines 16-25). Lisboa adds that other personal care products such as oral hygiene, shower, sun, foot, hand and skin products may be formulated in aerosolized form to reduce skin burning and irritation. (see col 1, lines 33-40; lines 60-col 2, line 3). Therefore, Lisboa suggests a general desire in the art to provide personal care products in the form of aerosolized topical preparations. Thus, Examiner has taken the view that the combined teachings of the references suggests that Lajoie's formulations may be applied topically via an aerosolized preparation to comply with customers' appeal and further reduce irritation caused to skin.

Even assuming *arguendo*, that one of ordinary skill in the art would have not construed such suggestions directly from the references; there is ample knowledge available to one of ordinary skill in the art provided by the cited references that would have motivated the skill in the art to add a propellant to Lajoie's formulation. Lajoie's compositions reduce skin irritability. (see col 4, lines 32-36). The use of propellants in Lisboa's compositions also reduces the skin irritation (see col 2, lines 1-2). Lisboa clearly advocates for use of micronized zinc oxide powder in his aerosolized formulations (col 8, lines 15-19). Therefore, there was knowledge available to one of

Art Unit: 1617

ordinary skill in the art at the time of invention that using a propellant for topical delivery of zinc oxide particles, fragrances or surfactants reduces skin irritation.


In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Here, the cited references are general knowledge available to one of ordinary skill in the art, not appellant's disclosure. Therefore, the rejection is not based on improper hindsight reasoning, rather, *prima facie* obviousness.

For the above reasons, it is believed that the rejections should be sustained.

Application/Control Number: 09/675,938
Art Unit: 1617

Page 13

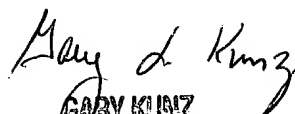
Respectfully submitted,



Shahnaz Sharareh, JD, PharmD
Patent Examiner
Art Unit 1617

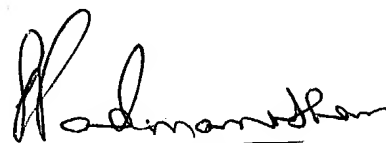
ss
November 16, 2004

Conferees



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER